

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

BIOGEN MA INC. and  
BIOGEN INTERNATIONAL NEUROSCIENCE  
GMBH,

Plaintiffs,

v.

ANDREI IANCU, UNDER SECRETARY OF  
COMMERCE FOR INTELLECTUAL  
PROPERTY AND DIRECTOR OF THE  
UNITED STATES PATENT AND  
TRADEMARK OFFICE,

Defendant.

Civil Action No.

**COMPLAINT**

Plaintiffs Biogen MA Inc. (“Biogen MA”) and Biogen International Neuroscience GmbH (“Biogen International”), (collectively, “Biogen” or “Plaintiffs”), by and through their undersigned counsel, for its Complaint against Mr. Andrei Iancu (“Defendant”), respectfully state as follows:

**NATURE OF ACTION**

1. This is an action by the owner and assignee of United States Patent No. 9,598,484 (“the ’484 patent”), brought pursuant to 35 U.S.C. § 154 (b)(4)(A) and 5 U.S.C. §§ 701-706 seeking judgment that the patent term adjustment (“PTA”) for the ’484 patent be changed from 0 days to 23 days.

2. This action arises under 35 U.S.C. § 154 (b)(4)(A) and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

### **THE PARTIES**

3. Biogen MA is a corporation organized and existing under the laws of the Commonwealth of Massachusetts with its principal place of business at 225 Binney Street, Cambridge, Massachusetts 02142.

4. Biogen International is a Swiss corporation with its principal place of business in Zug, Switzerland at Landis + Gyr-Strasse 3, 6300 Zug, Switzerland.

5. Defendant is the Under Secretary of Commerce for Intellectual Property and the Director of the United States Patent and Trademark Office (“PTO”), acting in his official capacity. The Director is the head of the agency, charged by statute with providing management supervision for the PTO and for the issuance of patents. The Director is the official responsible for determining the period of PTA under 35 U.S.C. § 154(b)(3).

### **JURISDICTION AND VENUE**

6. This Court has subject matter jurisdiction over this action and is authorized to issue the relief sought pursuant to 28 U.S.C §§ 1331, 1338(a) and 1361; 35 U.S.C. § 154(b)(4)(A); 28 U.S.C. § 2201; and 5 U.S.C. §§ 701–706.

7. Venue is proper in this district by virtue of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 9, 125 Stat. 316 (2011) and pursuant to 35 U.S.C. § 154(b)(4)(A).

8. This action is timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

### **BACKGROUND**

9. Paul H. Weinreb, Feng Chen, Ellen A. Garber, Jan Grimm, and Fabio Montrasio are the inventors of the invention claimed in U.S. Patent Application No. 14/654,176 (“the ’176 application”) entitled “Human Anti-Tau Antibodies,” filed on June 19, 2015. The ’176 application is the National Stage Entry of PCT US2013/076952, filed December 20, 2013,

claiming priority from the U.S. Provisional Application No. 61/745,410, filed December 21, 2012. The '176 application issued as the '484 patent on March 21, 2017. A true and correct copy of the '484 patent is attached hereto as **Exhibit A**. A true and correct copy of the relevant file history of the '176 application is attached hereto as **Exhibit B**.<sup>1</sup> A screen capture of the relevant "Transaction History" published by the USPTO on its Public Patent Application Information Retrieval website is attached hereto as **Exhibit C**.

10. Biogen MA and Biogen International are the owners and assignees of all right, title, and interest in the '484 patent, as evidenced by the assignment documents recorded with the PTO at Reel/Frames 038225/0292 and 038225/0268 on April 08, 2016, in which the inventors assigned all right, title, and interest to Biogen MA or Biogen International. Reel/Frames 038394/0924 recorded on April 08, 2016, 038464/0090 recorded April 19, 2016 and 038395/0409 also recorded on April 19, 2016 changed the name of ownership to Biogen MA or Biogen International. Biogen MA and Biogen International are the real parties-in-interest in this case.

#### **The Patent Term Adjustment Statute**

11. Under 35 U.S.C. § 154(a)(2), the grant of a patent is for a term ending 20 years from the effective filing date of the patent application. Because this twenty-year period begins to run before a patent is issued, any delay in the PTO's processing of an application reduces the duration of the patent term.

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<sup>1</sup> All page number citations relating to Exhibit B refer to the page numbers added to the bottom of each page of the '176 application file history. To limit the burden on the Court, prior art references, the patent and correspondence prior to the Notice of Allowability are excluded from the file history because they are voluminous and not relevant here.

12. To prevent undue PTO delays from decreasing patent term, Congress directed the PTO to grant successful applicants upward adjustments of their patent terms to compensate for three categories of processing delay by the PTO. These categories of delay, for which compensation is “Guarantee[d],” are set forth in 35 U.S.C. §§ 154(b)(1)(A), (B), and (C), and are commonly known as “A-delay,” “B-delay,” and “C-delay,” respectively. *A-delay* accrues when the PTO fails in certain specified ways to respond to the applicant in a timely fashion, such as by failing to provide a notification or notice of allowance within 14 months of the filing of the application or by failing to issue a patent within 4 months of the date on which the issue fee was paid. Next, *B-delay* accrues when the PTO fails to issue a patent within three years, excluding certain specified periods of time. Finally, *C-delay* accrues when there are delays “due to derivation proceedings, secrecy orders, and appeals.”

13. Section 154(b)(2)(C)(i) directs that “[t]he period of adjustment of the term of a patent under paragraph [154(b)(1)] shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” Such a period of time is commonly known as “applicant delay.”

14. At issue in this case is the PTO’s calculation of applicant delay.

15. Section 154(b)(2)(C)(iii) states that the “Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” Under the regulations promulgated by the Director, when patentee submits “an amendment . . . or other paper after a notice of allowance has been given or mailed, . . . the period of adjustment . . . shall be reduced by the lesser of: (i) The number of days, if any, beginning on the date the amendment . . . or

other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment . . . or such other paper; or (ii) Four months.” 37 CFR 1.704(c)(10).

16. Drawings submitted after a Notice of Allowance “will be considered a failure to engage in reasonable efforts to conclude processing or examination of an application” and may support the PTO’s finding of applicant delay. *See* MPEP § 2732.

17. The formula for calculating the total patent term adjustment to which an applicant is entitled is as follows: A-delay + B-delay + C-delay - overlap - applicant delay = PTA.

18. Under 35 U.S.C. § 154(b)(4)(A), “[a]n applicant dissatisfied with the Director’s decision on the applicant’s request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director’s decision on the applicant’s request for reconsideration.”

**Proceedings in the PTO with Respect to the ’484 Patent**

19. The proceedings in the PTO with respect to the ’484 patent are reflected in the administrative record and are summarized in relevant respects as follows.

20. The ’176 application was filed on June 19, 2015, and issued as the ’484 patent on March 21, 2017. (Ex. A.)

21. A Notice of Allowance was mailed for the present application on January 31, 2017. (Ex. B at 63.)

22. The PTO mailed a Notice to File Corrected Application Papers (“the Notice”) on February 7, 2017. The PTO identified certain drawing deficiencies and requested corrected drawings. (Ex. B at 29-31.)

23. On the same day, February 7, 2017, applicants submitted replacement drawings addressing every issue that the PTO had identified. (Ex. B at 36-37, 39, 62.)

24. Also on the same day, February 7, 2017, the PTO reviewed and accepted the corrected drawings, noting “02-07-2017 Workflow - Drawings Finished” in the Transaction History section of the PTO’s PAIR system. (Ex. C).

25. The PTO did not mail a notice in response to the submission of the corrected drawings. (Ex. B at 15.).

26. The PTO assessed the PTA at 0 days, as indicated on the face of the ’484 patent and in the Issue Notification mailed on March 01, 2017. (Ex. A; Ex. B at 28.)

27. On May 18, 2017, the patentee filed an Application for Patent Term Adjustment, requesting that the PTA for the ’484 patent be increased from 0 days to 23 days. (Ex. B at 19-21.)

28. On August 16, 2017, the PTO issued a Decision for Request for Reconsideration of Patent Term (“the Decision”), denying the request for reconsideration of the 0 day PTA. The Decision maintained that the patent is entitled to 0 days of PTA. (Ex. B at 11-16.)

29. On October 10, 2017, the patentee filed a Petition to Invoke the Supervisory Authority of the Director, requesting that the Director review the Decision and modify the PTA to 23 days. (Ex. B at 5-8.)

30. On December 26, 2017, the PTO issued a Letter stating that the PTO’s Decision denying the request for PTA of 23 days represented the conclusion of the consideration by the USPTO. The Letter maintained that the patent is entitled to 0 days of PTA. (Ex. B at 1-3.)

### **The Challenged PTO Determination of PTA**

#### **The PTO's Incorrect Calculation of Patent Term Adjustment**

31. Biogen and the PTO both agree that the period of A-delay is 24 days, there are 0 days of B-delay, C-delay, and overlap days, respectively. Biogen and the PTO disagree only as to the period of applicant delay.

32. The PTO acknowledged in the Decision that “no paper was mailed on February 7, 2017, in response to the corrected drawings filed on February 7, 2017, or on any date other than March 21, 2017, the date that the patent issued.” (Ex. B at 15).

33. The PTO arbitrarily determined that in the absence of the PTO's mailing a notice to mark the end of the period of delay associated with submission of replacement drawings, the patent issue date was the acceptable substitute to mark the end of the delay period.

34. The PTO erroneously charged 43 days of applicant delay for the response to the Notice, measured from the date the replacement drawings were filed, February 7, 2017, until the date the patent issued, March 21, 2017.

35. The PTO's improper calculation of applicant delay led to an incorrect determination of 0 days of PTA. The PTO arrived at this determination of PTA based on the following calculation: (A-delay: 24 + B-delay: 0 + C-delay: 0) – (Overlapping days: 0) – (“Applicant's delay”: 43) = 0 days. The PTO's determination of PTA was therefore contrary to section 154(b)(1).

#### **The Correct Calculation of Patent Term Adjustment for the '484 patent**

36. The proper amount of applicant delay is 1 day. The PTO requested corrected drawings after the Notice of Allowance, appropriately starting the delay period. Yet on the same day, the applicants transmitted to the PTO the requested corrected drawings and the PTO

reviewed and accepted the corrected drawings, resulting in a delay of patent issuance of at most 1 day.

37. The '484 patent is entitled to a PTA of 23 days, based on a period of A-delay of 24 days, a period of B-delay of 0 days, a period of C-delay of 0 days, a period of Overlap of 0 days, and a period of Applicant delay of 1 day.

38. The correct calculation of PTA is as follows: (A-delay: 24 + B-delay: 0 + C-delay: 0) – (Overlapping days: 0) – (“Applicant’s delay”: 1) = 23 days.

39. The PTO’s determination that the '484 patent is entitled to 0 days of PTA is incorrect because it counts 43 days of applicant delay, rather than the correct value of 1 day of applicant delay. Therefore, the PTO should have determined that the '484 patent is entitled to 23 days of PTA.

**COUNT ONE: Adjustment of Patent Term under 35 U.S.C. § 154(b)**

40. The allegations of paragraphs 1 – 39 are incorporated in this claim for relief as if fully set forth herein.

41. The '484 patent, which was assigned to Biogen MA and Biogen International, issued on March 21, 2017. The Defendant, by the Petition Decision dated August 16, 2017, erroneously determined the PTA for the '484 patent to be 0 days.

42. Defendant’s Petition Decision dated August 16, 2017, is a final agency decision within the meaning of 5 U.S.C. § 704 for the purposes of seeking judicial review.

43. The Defendant erroneously determined that the '484 patent is entitled to a PTA of 0 days, based on a period of A-delay of 24 days, a period of B-delay of 0 days, a period of C-delay of 0 days, a period of Overlap of 0 days, and a period of Applicant delay of 43 days ((A-delay: 24 + B-delay: 0 + C-delay: 0) – (Overlapping days: 0) – (“Applicant delay”: 43) = 0 days).



The Defendant erred in that calculation based on the Defendant's erroneous calculation of applicant delay.

44. The correct PTA for the '484 patent is 23 days, based on a period of A-delay of 24 days, a period of B-delay of 0 days, a period of C-delay of 0 days, a period of Overlap of 0 days, and a period of Applicant delay of 1 day ((A-delay: 24 + B-delay: 0 + C-delay: 0) – (Overlapping days: 0) – (“Applicant delay”: 1) = 23 days).

45. The '484 patent is not subject to a terminal disclaimer, so the provisions of 35 U.S.C. § 154(b)(2)(B) do not apply, and the full period of PTA should be granted.

46. The Defendant's determination that the '484 patent is entitled to 0 days of PTA is arbitrary, capricious, an abuse of discretion, clear error or otherwise not in accordance with law and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

47. Biogen is thus entitled to additional patent term for the '484 patent, such that the 0 days of PTA granted by the PTO should be changed to 23 days.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff Biogen, respectfully prays that this Court:

(A) Issue an Order declaring that the correct period of PTA for the '484 patent is 23 days, and setting aside the prior determination of the PTO;

(B) Issue an Order compelling the Defendant forthwith to change the period of the PTA for the '484 patent to 23 days, and compelling the Director to extend the term of the '484 patent to reflect the 23 days of patent term adjustment;

(C) Issue an award of Biogen's reasonable attorney fees, expenses and costs of suit, in accordance with 28 U.S.C. § 2412, 35 U.S.C. § 285, and other applicable law; and

(D) Grant such other and further relief as the nature of this case may admit or require and as may be just and equitable.

Dated: February 9, 2018

/s/ Ahmed J. Davis

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**CERTIFICATE OF SERVICE**

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on this 9<sup>th</sup> day of February, 2018.

/s/ Ahmed J. Davis

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